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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/724,538	11/28/00	SHOEMAKER	D 9301-123

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HM12/1109

EXAMINER
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LU, F

ART UNIT	PAPER NUMBER
1655	5

DATE MAILED: 11/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/724,538

Applicant(s)

SHOEMAKER ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-213 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-213 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Location of Application***

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1655.

***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-36, 45, 46, 86-90, 157-183, and 212, drawn to a method for analyzing exon expression in a cell sample, classified in class 435, subclass 91.1.
  - II. Claims 37, 39-46, 83, 84, 86-90, 151-156, 182-185, and 212, drawn to a method for analyzing exon expression in a cell sample, classified in class 435, subclass 91.1.
  - III. Claims 38-46 and 212, drawn to a method for determining the presence or absence of alternatively spliced mRNAs for a plurality of genes in a cell sample, classified in class 435, subclass 91.51.
  - IV. Claims 47, 50-82, 85, 86-90, and 212, drawn to a method for determining the exon expression state of a cell sample, classified in class 435, subclass 91.1
  - V. Claims 48 and 49, drawn to a method for determining the exon expression state of a chromosome of an organism in a cell sample, classified in class 435, subclass 91.1.

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- VI. Claims 91, 92, and 97-127, drawn to an array comprising a positionally-addressable array of polynucleotide probes bound to a support, classified in class 435, subclass 287.2.
- VII. Claims 93, 94, and 97-128, drawn to an array comprising a positionally-addressable array of polynucleotide probes bound to a support, classified in class 435, subclass 287.2.
- VIII. Claims 95-127, drawn to an array comprising a positionally-addressable array of polynucleotide probes bound to a support, classified in class 435, subclass 287.2.
- IX. Claims 129-133, drawn to a set of positionally-addressable array of polynucleotide probes, classified in class 536, subclass 23.1.
- X. Claims 134 and 136, drawn to a method for preparing an array of polynucleotide probes, classified in class 435, subclass 287.2.
- XI. Claims 135 and 137, drawn to a method for preparing an array of polynucleotide probes, classified in class 435, subclass 287.2.
- XII. Claim 138-145, drawn to a method for determining the relative level of expression of individual exons in a gene, classified in class 435, subclass 91.1.
- XIII. Claims 146-150, drawn to a method for detecting alternative splicing between two cell samples of a species of an organism, classified in class 435, subclass 91.1.
- XIV. Claims 186-196, drawn to a method for determining the effect of a perturbation on RNA splicing pathways in a gene, classified in class 435, subclass 91.51.
- XV. Claim 197, drawn to a computer system, classified in class 702, subclass 19.

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XVI. Claim 198, drawn to a computer system, classified in class 702, subclass 19.

XVII. Claims 199-201, drawn to a computer system (claims 199 and 200) and a database (claim 200), classified in class 702, subclass 19.

XVIII. Claims 202-204, drawn to a method for selecting polynucleotide probes for preparation of an array for exon profiling, classified in class 435, subclass 91.1.

XIX. Claim 205-213, drawn to a method for identifying differences in exon or multiexon expression levels, classified in class 435, subclass 91.1.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I, II, III, IV, V, X, XI, XII, XIII, XIV, XVIII, and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different methods or methods with different method steps that have different modes of operation, different functions, or different effects.

Groups I, II, III, IV, V, XII, XIII, XIV, XIX, and XX (method claims) and groups VI, VII, VIII, and IX (product claims) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as PCR.

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Groups X (method claim) and Groups VI, VII, VIII, and IX (product claims) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as the method in Group XI.

Groups XI (method claim) and Groups VI, VII, VIII, and IX (product claims) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as the method in Group X.

Groups I, II, III, IV, V, X, XI, XII, XIII, XIV, XVIII, and XIX (method claims) and groups XV, XVI, and XVII (product claim) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are directed to different methods and unrelated products that have different modes of operation, different functions, or different effects.

Groups VI, VII, VIII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case,

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these inventions are directed to different arrays with different compositions that have different modes of operation, different functions, or different effects.

Groups VI, VII, VIII, and IX (arrays) and Groups XV, XVI, and XVII (computer and database) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different products that have different modes of operation, different functions, or different effects.

Groups XV, XVI, and XVII (computer and database) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different computer systems or computer systems with different execution steps that have different modes of operation, different functions, or different effects.

4. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper as following reasons:

(1) the search required for Group I such as wherein the measured expression level of each exon or multiexon is not averaged with the measured expression level of one or more different exons or multiexons in the same gene is not required for Groups II to XIX;

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- (2) the search required for Group III such as wherein said plurality of exons is sufficient to distinguish a plurality of alternatively splicing pathways is not required for Groups I, II, IV to VIII, and X to XIX;
- (3) the search required for Group IV such as representing the exon expression state of said cell sample as a collection of individual values of said measured expression level for each exon or multiexon in said plurality of individual exons or multiexons is not required for Groups I to III and V to XX;
- (4) the search required for Group V such as chromosome is not required for Groups I to IV and VI to XIX;
- (5) the search required for Group VI such as junction specific probe is not required for Groups II, III, V, and X to XX;
- (6) the search required for Group VII such as a positionally-addressable array is not required for Groups XV to XVII;
- (7) the search required for Group VIII such as wherein the plurality of different exons or multiexons for each of said different genes comprises a set of exons that is sufficient to distinguish a plurality of alternative splicing pathway is not required for Groups I, II and IV to XIX;
- (8) the search required for Group IX such as each of all known or predicted exons or multiexons in the genome of an organism is not required for Groups I to IX and X to XIX;
- (9) the search required for Group X such as synthesizing a plurality of polynucleotide probes of different nucleotide sequences on a support is not required for Groups I to IX and XI to XIX;



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- (10) the search required for Group XI such as depositing a plurality of polynucleotide probes on a support is not required for Groups I to X and XII to XIX;
- (11) the search required for Group XII such as determining the relative level of expression of individual exons in a gene is not required for Groups I to XI, XIII, XIV, and XVI to XIX;
- (12) the search required for Group XIII such as detecting alternative splicing between two cell samples of a species of an organism is not required for Groups I to XII , XIV to XVI, XVIII and XIX;
- (13) the search required for Group XIV such as a perturbation on RNA splicing pathways in a gene is not required for Groups I to XIII and XV to XIX;
- (14) the search required for Group XV to XVII such as a computer system is not required for Groups I to XIII, XVIII, and XIX;
- (15) the search required for Group XVIII such as steps (c) and (d) in claim 202 is not required for Groups I to XVII and XIX;
- (16) the search required for Group XIX such as plurality of cell sample is not required for Groups I to XII and XIV to XIX;
- (17) different classification among different groups
  - a. Groups I to VIII, X to XIV, XVIII, and XIX(class 435);
  - b. Group IX (class 536);
  - c. Groups XV to XVII (class 702).

Papers related to this application may be submitted to Group 1600 by facsimile transmission.

Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The

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faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu  
November 6, 2001

  
**ETHAN C. WHISENANT**  
**PRIMARY EXAMINER**